Follow-up of successful bilateral placement of Essure microinserts with ultrasound.

S. Veersema
M.P.H. Vleugels
A. Timmermans
H.A.M. Brölmann

Abstract

Objective To evaluate the reliability of pelvic X-ray and transvaginal ultrasound to localize Essure microinserts (Conceptus, San Carlos, California) after successful placement in both fallopian tubes 3 months after placement.

Design Prospective, observational study.

Setting Gynecology departments at two teaching hospitals.

Patient(s) One hundred eighty-two patients who underwent hysteroscopic sterilization by placement of Essure microinserts between August 2002 and August 2004.

Intervention(s) Transvaginal ultrasound, pelvic X-ray, and hysterosalpingography (HSG) 3 months after sterilization with Essure.

Main Outcome Measure(s) Transvaginal ultrasound confirmation of correct localization of microinserts after a 3-month follow-up.

Result(s) In 150 of 182 patients, confirmation of successful bilateral placement of two microinserts (300 devices) was possible. In 9 patients it was not possible to identify both devices with ultrasound, or there was doubt about the extension of the device through the uterotubal junction. The other 291 devices were identified as being in a good position.

Conclusion(s) Hysterosalpingography at the 3-month follow-up after successful placement of Essure microinserts can be replaced by transvaginal ultrasonography. A 3-month follow-up with HSG after the Essure procedure is only required after unsatisfactory placements. In those patients in whom transvaginal ultrasonography cannot confirm satisfactory localization, a complementary pelvic X-ray should be performed.

Key Words Essure, hysteroscopic sterilization, hysterosalpingography, pelvic X-ray, transvaginal ultrasound
Introduction

Essure is a new device for hysteroscopic tubal sterilization. The Essure System (Conceptus, San Carlos, CA) was approved by the European Health Office in November 2001 and by the U.S. Food and Drug Administration in November 2002. It is an expanding spring device made of a nickel–titanium outer coil and a flexible stainless steel inner coil with Dacron fibers. This microinsert is placed in the proximal section of the fallopian tube under hysteroscopic visualization. The Dacron fibers cause localized tissue ingrowth from the surrounding tube, thereby achieving mechanical occlusion of the tube. The tissue response is the result of a chronic inflammatory and fibrotic response to the fibers. Over a 3-month period this ingrowth completely occludes the tubal lumen.

The effectiveness of the Essure microinsert in preventing pregnancy is believed to be due to a combination of the space-filling design of the device and this local, occlusive, benign tissue response to the fibers. This tissue ingrowth in the devices, caused by the fibers, results in both device retention and pregnancy prevention (1).

Initially all patients were scheduled for hysterosalpingography (HSG) 3 months after an Essure microinsert placement procedure (2,3). The HSG was performed to evaluate microinsert location and fallopian tube occlusion. Until the Essure sterilization was completed after 3 months and confirmed by HSG, all patients were advised to use alternative contraception.

Because of the potential risks, higher cost, inconvenience, and discomfort of the required HSG, clinical data of 700 patients included in a phase II trial were reviewed (4). This included a review of HSGs, radiographs, and videotapes of all the procedures in which the HSG detected a potential problem. On the basis of this review, criteria were developed for identifying the small proportion of patients who might benefit from an HSG evaluation, on the basis of their 3-month pelvic X-ray results. The current recommendation is to check the position and alignment of the microinserts with pelvic X-ray 3 months after a satisfactory bilateral placement. Satisfactory placement involves good visualization of the tubal ostia and microinsert location across the uterotubal junction, with 3–10 visible expanded coils trailing into the uterus. Hysterosalpingography is only requested in cases of no placement, unilateral placement, or incorrect placement (>10 device loops outside the tubal lumen) (4,5). In cases of satisfactory bilateral one-step placement, X-ray showed 100% correct position of both devices (5). In another report (4), only one patient had abnormal X-ray findings (too much distance between the two devices) after satisfactory bilateral placement. Hysterosalpingography revealed tubal occlusion. Therefore, in cases of optimal placement, 100% bilateral occlusion was detected with X-ray only (5).
Although X-ray seems to be a sensitive test in detecting the microinserts, limited information is gained about the soft tissue structures that envelope it. Ultrasound seems to be well suited for microinsert localization. It has many advantages over X-ray. Ultrasound has the ability to locate the device and visualize its relationship with the surrounding tissue. The position of the device within the uterotubal junction can be displayed on ultrasound, whereas it can be merely inferred on plain X-ray films. Ultrasound provides real-time and dynamic imaging information to aid with device location, whereas X-ray provides a single, static image. Importantly, ultrasound is a nonionizing method of imaging that potentially can be performed in the doctor’s office without the need for an extra visit to a radiology department, thus shifting and reducing follow-up expenses. An early post-insertion ultrasound can even be used to ensure correct positioning of the device or its eventual malposition.

In an earlier study, 5 patients were examined by ultrasound within 4 weeks after insertion. Fourteen pairs of devices were seen. One device was malpositioned, and in 1 patient a device was missing (6).

In this study, we assessed the test characteristics of transvaginal ultrasonographic localization of the microinserts, compared with pelvic X-ray and HSG.

**Figure 1**
Transvaginal ultrasound at 3 months. (A) Microinsert crossing the cornua of the uterus, with the proximal end in the uterine wall. (B) Transverse section of the uterus demonstrating both microinserts.
Materials and methods

Between August 2002 and August 2004, 182 consecutive patients were included in the clinical evaluation of the Dutch Essure trial in two clinics in the Netherlands (St. Antonius Hospital Nieuwegein and the Rivierenland Hospital Tiel). In both clinics the investigators followed the same study protocol and obtained approval from the clinical and ethics committees. All women gave their written, informed consent in the knowledge that this new method of sterilization is irreversible, and data of a long-term follow-up are not yet available. In 150 women (82.4%), a successful bilateral Essure placement in a one-step procedure was achieved. These patients were advised to continue alternative contraception for the next 3 months and were scheduled for transvaginal ultrasound after 3 months. Transvaginal ultrasound was followed by HSG in that same session. Hysterosalpingography was started with a blank abdominal X-ray. Ultrasound was performed with an Aloka SSD 550 (Biomedic Nederland BV, Almere) or a Toshiba Eccobee (Toshiba Medical Systems Nederland BV, Zoetermeer).

After the microinserts were localized by ultrasound, the position of the reflections of the microinsert in relation to the outer line of the uterus was described. The position of the devices was “satisfactory” when the reflections of the microinsert crossed the outer line of the uterine wall and the proximal ends of both devices were visualized inside the outer line or in the region of the endometrial cavity (Fig. 1). The physician was asked to predict the occlusion of each fallopian tube, which was confirmed by HSG. The criteria used to evaluate the HSG for “satisfactory” placement were [1] both microinserts visible with ≤50% of the length of the inner coil trailing into the cavity, [2] the proximal ends of the inner coils appear to be <30 mm into the tube from where contrast fills the uterine cornua, and [3] no contrast visible in the tubes beyond the microinserts or in the peritoneal cavity (7).

The pelvic X-ray was “satisfactory” when the microinserts appeared to be in the tubal lumen, spanning the uterotubal junction, and relatively symmetrical.

All data were collected with commercial statistical software (SPSS, Chicago, IL). Sensitivity, specificity, positive predictive value, and negative predictive value for transvaginal ultrasound and X-ray were calculated. Hysterosalpingography was considered the “gold standard”.

Results

In 150 patients with successful bilateral placement, 2 microinserts (300 devices) could be examined by transvaginal ultrasound. In 9 patients it was not possible to identify both devices with ultrasound, or there was doubt as to the extension of the device through the uterotubal junction. The other 291 devices were identified and in a good position. In 1 of the 9 patients with unsatisfactory ultrasound results only 1 microinsert was present on pelvic X-ray; this patient seemed to have had an expulsion (Fig. 2). In 149 patients the pelvic X-ray was determined to be satisfactory with both microinserts. One of these 149 women was found to have some evidence of dye passage (patency) past the microinsert into the distal tubal lumen upon HSG (Fig. 3). This patient refused to continue the use of alternative contraception and insisted on sterilization. Forty-nine weeks later she underwent a repeat HSG, and bilateral tubal occlusion was achieved at this time. This patient did not become pregnant despite unprotected sexual intercourse. One hundred forty-eight patients were instructed to discontinue alternative contraception because of bilateral tubal occlusion 3 months after the procedure. In the patient with the expulsion a second microinsert was placed in a new attempt. The patient continued with alternative contraception for 3 more months, and HSG was repeated.

The results of transvaginal ultrasound as compared with the results of HSG as the “reference test” show a sensitivity of 50% and a specificity of 95%. Compared with pelvic X-ray as the reference test these values are 100% and 95%, respectively. The predictive value of a satisfactory transvaginal ultrasound result is 99% and the predictive value of an unsatisfactory result is 11%.
Discussion

The 3-month follow-up period after hysteroscopic sterilization with Essure is based on the time it takes the tissue ingrowth to completely occlude the tubal lumen (1). Because the initial recommendation of an HSG has been changed to pelvic X-ray 3 months after successful bilateral placement, exclusion of tubal patency is no longer a requirement (4). After satisfactory pelvic X-ray results, the patient can rely on the microinserts for sterilization (7). In the present study, ultrasound detection of both devices was satisfactory in 141 of the 150 patients with successful bilateral placement. One patient with an expulsion of a microinsert was recognized with ultrasound as well as with pelvic X-ray. A second patient with tubal patency on HSG had a satisfactory pelvic X-ray, and both devices were in a good position on transvaginal ultrasound. It has been postulated that the absence of absolute physical occlusion of the tubes does not necessarily equate with failure of sterilization. In only 8 patients with satisfactory pelvic X-ray results was it not possible to confirm the satisfactory position of the devices with transvaginal ultrasound. Transvaginal ultrasound has great advantages over pelvic X-ray because it is a non-ionizing method of imaging. It can be done on an outpatient basis in departments of gynecology by the patient’s own physician and can be repeated at any time without any risk to the patient.

We conclude that HSG at the 3-month follow-up of hysteroscopic sterilization with Essure can be replaced by transvaginal ultrasound. In those patients for whom transvaginal ultrasound cannot confirm satisfactory localization, a complementary pelvic X-ray should be performed.

Figure 2
Hysterosalpingogram at 3 months: note correct placement of both devices and patency of the right fallopian tube.
Hysterosalpingography is only required after unsatisfactory placements. The number of HSGs and pelvic X-rays can be minimized, thus reducing costs, inconvenience, and discomfort. In cases of technical difficulties during the procedure or for patients with abnormal bleeding after the insertion, a transvaginal ultrasound can be scheduled 4 weeks after the procedure. This will prevent unnecessary anxiety in these women and offers the possibility of preventing a potential delay in diagnosing expulsion or misplacement of a microinsert.

References